

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of:

**Dean A. Schaefer, et al**

**Serial No.:** Not Yet Assigned; a continuation  
application of co-pending application S.N.  
09/897,483, filed July 2, 2001

**Filed:** Herewith

**For:** TUMOR ABLATION NEEDLE WITH  
INDEPENDENTLY ACTIVATED AND  
INDEPENDENTLY TRAVERSING TINES

)  
)  
) **Group Art Unit:** 3739 (Parent Appl)

)  
) **Examiner:** Michael Peffley (Parent  
) Appl)

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
Alexandria, VA 22313-1450

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO/SB/08A (08-00). Copies are not enclosed since each item was submitted or cited in a parent application (Serial No. 09/897,483).

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d) or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.

☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

**STATEMENT UNDER 37 CFR § 1.97(e):**

☐ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.

☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above fee(s).  
☐ Please charge \_\_\_\_\_ to Deposit Account No. **50-2518** for the above fee(s).

The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Bingham McCutchen's Deposit Account No. **50-2518**.

Dated: 9/15/03

Respectfully submitted,  
BINGHAM McCUTCHEN LLP  
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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	
				Filing Date	
				First Named Inventor	
				Group Art Unit	
				Examiner Name	
Sheet 1 of 3				Not-Yet-Assigned Herewith Dean A. Schaefer, et al 3739 (Parent Appl) Michael Peffley (Parent Appl) 2024728-7031453001 (00-011US2)	

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	1.	5,672,173		Gough et al.	09-30-1997	
	2.	5,672,174		Gough et al.	09-30-1997	
	3.	5,728,143		Gough et al.	03-17-1998	
	4.	5,741,225		Lax et al.	04-21-1998	
	5.	5,782,827		Gough et al.	07-21-1998	
	6.	5,800,484		Gough et al.	09-01-1998	
	7.	5,810,804		Gough et al.	09-22-1998	
	8.	5,827,276		LeVeen et al.	10-27-1998	
	9.	5,855,576		LeVeen et al.	01-05-1999	
	10.	5,863,290		Gough et al.	01-26-1999	
	11.	5,868,740		LeVeen et al.	02-09-1999	
	12.	5,913,855		Gough et al.	06-22-1999	
	13.	5,925,042		Gough et al.	07-20-1999	
	14.	5,928,229		Gough et al.	07-27-1999	
	15.	5,935,123		Edwards et al.	08-10-1999	
	16.	5,951,547		Gough et al.	09-14-1999	
	17.	5,954,717		Behl et al.	09-21-1999	
	18.	5,980,517		Gough et al.	11-09-1999	
	19.	6,041,260		Stern et al.	03-21-2000	
	20.	6,050,992		Nichols	04-18-2000	
	21.	6,053,937		Edwards et al.	04-25-2000	
	22.	6,059,780		Gough et al.	05-09-2000	
	23.	6,071,280		Edwards et al.	06-06-2000	
	24.	6,077,261		Behl et al.	06-20-2000	
	25.	6,080,149		Huang et al.	06-27-2000	
	26.	6,080,150		Gough et al.	06-27-2000	
	27.	6,090,105		Zepeda et al.	07-18-2000	
	28.	6,235,023		Lee et al.	05-22-2001	

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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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OTHER DOCUMENTS -- NON PATENT LITERATURE			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and-or country where published.	T <sup>2</sup>
	BB	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF 2000™ Generator and the LeVeon™ Needle Electrode" 1. Abstract: Soulen, et al., "Oral Presentation at the SCVIR," March 20-15, 1999, in <u>Radiofrequency Energy: Clinical Applications</u> , Radio Therapeutics Corporation	
	BC	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF 2000™ Generator and the LeVeon™ Needle Electrode" 2. Abstract: Bauer, et al., "Radiofrequency Ablation Therapy for Large, Complex Hepatic Metastases," 52 <sup>nd</sup> Annual Mtg. Of Society of Surgical Oncologists, March 4-7, 1999, in <u>Radiofrequency Energy: Clinical Applications</u> , Radio Therapeutics Corporation	
	BD	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF 2000™ Generator and the LeVeon™ Needle Electrode" 3. Abstract: Birdwell, et al., "Preliminary Experience with Intraoperative Radiofrequency Breast Tumor Ablation," 84 <sup>th</sup> Annual Mtg. Of the Radiology Society of North America, November 29-December 4, 1998 in <u>Radiofrequency Energy: Clinical Applications</u> , Radio Therapeutics Corporation	
	BE	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF2000™ Generator and the LeVeon™ Needle Electrode" 4. Abstract: Curley, et al., "Freeze or Fry: A Comparison of Cryoablation and Radiofrequency Ablation for Malignant Liver Tumors," 49 <sup>th</sup> Annual Mtg. Of the American Association for the Study of Liver Diseases, 11-6-11-10, 1998 in <u>Radiofrequency Energy: Clinical Applications</u> , Radio Therapeutics Corporation	
	BF	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF2000™ Generator and the LeVeon™ Needle Electrode" 5. Abstract: Gantert et al., "Radiofrequency Ablation of Malignant Liver Tumors: Development of a New Multi-Array Electrode and Results of the First Human Treat-and-Resect Trials," 51 <sup>st</sup> Annual Mtg. Of the Society of Surgical Oncologists, 3-26-3-29, 1998 in <u>Radiofrequency Energy: Clinical Applications</u> , Radio Therapeutics Corporation	
	BG	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF2000™ Generator and the LeVeon™ Needle Electrode" 6. Abstract: Gandhi et al., "MR-Guided Radio Frequency Ablation of Breast Tissue Preliminary Results in a Mixed Fat-Water Tissue Phantom," 23 <sup>rd</sup> Annual Mtg. Of the Society of Cardiovascular & Interventional Radiologists, 2-28-3-5-1998	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<div style="float: left; width: 40%;"><p>Substitute for form 1449A/PTO</p><h2 style="text-align: center; margin: 10px 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2><p style="text-align: center; margin: 10px 0;">(use as many sheets as necessary)</p></div> <div style="float: right; width: 60%; border: 1px solid black; padding: 5px;"><p style="text-align: center; margin: 0;"><b>Complete if Known</b></p><table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%;">Application Number</td><td style="width: 50%;">Not-Yet-Assigned</td></tr><tr><td>Filing Date</td><td>Herewith</td></tr><tr><td>First Named Inventor</td><td>Dean A. Schaefer, et al</td></tr><tr><td>Group Art Unit</td><td>3739 (Parent Appl)</td></tr><tr><td>Examiner Name</td><td>Michael Peffley (Parent Appl)</td></tr><tr><td>Attorney Docket Number</td><td>2024728-7031453001 (00-011US2)</td></tr></table></div>				Application Number	Not-Yet-Assigned	Filing Date	Herewith	First Named Inventor	Dean A. Schaefer, et al	Group Art Unit	3739 (Parent Appl)	Examiner Name	Michael Peffley (Parent Appl)	Attorney Docket Number	2024728-7031453001 (00-011US2)
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	BH	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF2000™ Generator and the LeVein™ Needle Electrode" 7. Abstract: LeVein et al., "Large RF Ablation Lesion Produced with a Radially Expanding Monopolar Array Electrode: Long-term Porcine Experiments," 22 <sup>nd</sup> Annual Mtg. Of Society of Cardiovascular & Interventional Radiology, 03-8-13, 1997	
	BI	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF2000™ Generator and the LeVein™ Needle Electrode" 8. Abstract: LeVein et al., "Large Volume Porcine Liver Ablation with Use of a Percutaneous Expandable Electrosurgical Probe," 21 <sup>st</sup> Annual Mtg. Of Society of Cardiovascular & Interventional Radiology, 03-27-3-7, 1996	
	BJ	Radiotherapeutics Corporation, "Radiofrequency Energy: Clinical Applications – Previously presented data from experiences with the RF2000™ Generator and the LeVein™ Needle Electrode" 9. Curley, "Case Study: Radiofrequency-induced necrosis of liver tissue - Nectoris zones 1 and 6 months after the procedure,"	
	BK	Curley, "Radiofrequency Ablation of Unresectable Primary and Metastatic Hepatic Malignancies", Anals of Surgery, pp 1-8: 130(1), 1999	
	BL	Lawson, "Radiofrequency-induced Necrosis in Soft Tissues, A review of Deployments in Animals and Humans,"	
	BM	Lawson, "Radiofrequency-induced Necrosis in Soft Tissues, A Result from Animal and Human Deployments," Radio Therapeutics Corporation	
	BN	LeVein, "Laser Hyperthermia and Radiofrequency Ablation of Hepatic Lesions," Seminars in Interventional Radiology, pp 313-324: 14 (3), 1997	
	BO	RTC Training Manual, Chapters 1-9	

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